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09/851,664	05/09/2001	Robert De Leys	11362.0025.DVUS03	4387

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/851,664	DE LEYS ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,37-41 and 45-47* is/are pending in the application.

4a) Of the above claim(s) *38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,37,41 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 11-25-2005 are acknowledged. Claims 31 and 41 have been amended. Claims 42-44 have been canceled. Claims 45-47 have been added. Claims 31, 37-41 and 45-47 are pending. Claims 38-40 remain withdrawn from consideration as being drawn to non-elected inventions. Claims 31, 37, 41 and 45-47 are currently under examination.

Claim Rejections Withdrawn

The new matter rejection of claims 42-44 are rejected under 35 U.S.C. 112, first paragraph, is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claim 42-44 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "stringent conditions comprise conditions at least as stringent as..." is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 42-43 under 35 U.S.C. 102(b) as being anticipated by Montagnier et al. (WO 86/02383 – IDS- 5/9/2001) is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 31, 41 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action in the rejection of claims 31 and 41-43.

Applicant argues:

1. As amended, claim 41 now describes using a DNA probe that comprises a sequence that is identical to all or a portion of the cDNA corresponding to the entire RNA of the HIV-3....".

2. SEQ ID NO:1 is disclosed to have successfully detected the claimed HIV-3 strain.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, as stated in the rejection, the specification discloses SEQ ID NO:1 that corresponds to a portion of the HIV-3 cDNA (iso 70-11 clone). SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph (which is why claims 37 and 45 were not included in the rejection). However, the aforementioned claims encompass the vast genus of probes that merely have a single nucleotide in common with the cDNA corresponding to any RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. This vast genus fails to meet the written description provision of 35 USC 112, first paragraph.

With regard to Point 2, the instant claims encompass the detection of any HIV-3 isolate not just the isolate deposited at the ECACC under NO. V88060301. Moreover, the specification is silent with regard to the degree SEQ ID NO:1 is conserved among HIV-3 isolates.

As outlined previously, the specification discloses SEQ ID NO:1 that corresponds to a portion of the HIV-3 cDNA (iso 70-11 clone). SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph. However, the aforementioned claims are directed to encompass that merely have a single nucleotide in common with the cDNA corresponding to any RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfil the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Moreover, while SEQ ID NO:1 is disclosed, the specification is silent as to whether said sequence will meet the functional limitations (full breadth) of the rejected claims. Therefore, there are no disclosed probe sequences that meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Enablement Rejection

Claims 31, 37, 41 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the previous Office action in the rejection of claims 31, 37 and 41-44. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The amended claim language with regard to stringent conditions overcomes the Examiner's concerns as the specific disclosure of hybridization conditions enables the skilled artisan to perform the claimed process.

2. Applicant discloses a precise method for making and using the HIV-3 derived probes using standard methods and commercially-available reagents. Consequently, the skilled artisan would have little difficulty in creating probes from the deposited virus.

3. The disclosed protocol and the identity of SEQ ID NO:1 is sufficient to overcome the requirements form making the claimed probes via the claimed process.

4. The Examiner's argument that the probes may read on intact genomic material comprising enhancers, promoters, introns and splice cites is of little or no consequence as probes generated by the claimed method which hybridize to such regions can still be used for differential detection of the HIV-3 variant.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 2, the probes of claimed invention are not limited to those derived **from** the deposited material. They encompass all probes that hybridize **to** the genomic RNA of the deposited material.

With regard to Point 3, the probe engendered by SEQ ID NO:1 constitutes a single species in a vast genus of probes and as such is insufficient to provide enablement for the full breadth of the rejected claims. It should be noted that the aforementioned claims encompass the vast genus of probes that merely have a single nucleotide in common with the cDNA corresponding to any RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301

With regard to Point 4, a given probe can only differentially detect a HIV-3 isolate if the probe binds to a region unique to HIV-3.

As outlined previously, claims 31, 37, 41 and 45-47 encompass polynucleotides (DNA probes) comprising non-disclosed nucleic acid sequences that merely have a single nucleotide in common with the cDNA corresponding to any RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Claims 37 and 45 are drawn to DNA probes comprising/consisting of SEQ ID NO:1 or the complement of SEQ ID NO:1. As disclosed above, the specification does not teach how to make any polynucleotides that is identical s to the cDNA corresponding to the RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301 (i.e. the probes have not been identified). Clearly, since the specification has not taught how to make/use said polynucleotides, the specification has not enabled the instant claims that require DNA probes. Said probes include those comprising SEQ ID NO:1 or the complement of thereof. When given

the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Moreover, the use of the terms "comprising" (claims 37, 41 and 46) and "contains" (claim 31) read on intact genomic material comprising enhancers, promoters, introns, and splice sites, etc. No open reading frames are identified in any sequence such that one of skill in the art would be able to determine where such features could be within the sequence. Clearly, it would be expected that a substantial number of the hybridizing or complementary polynucleotides encompassed by the claims would not share either structural or functional properties with polynucleotides that encode SEQ ID NO:1 or its complement. The specification fails to provide an enabling disclosure for how one would make such polynucleotides. Moreover, the specification is silent as how one would detect a non-genomic RNA species using a probe that hybridizes to genomic RNA. The specification provides insufficient guidance with regard to these issues and provides no working examples that would provide guidance to one skilled in the art on how to make/use the broadly claimed genus. For the above reasons, undue experimentation would be required to practice the claimed invention. Hence, the rejection is deemed proper and is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 37, 41 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is rendered vague and indefinite by the use of the term "corresponding to" It is unclear what criteria are used to determine said correspondence. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41 and 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog (1991).

The Stratagene catalog discloses a random primer set that consists of every possible 9-mer primers (see page 66). These would necessarily include those nucleic acids that would bind to cDNA corresponding to an RNA the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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ROBERT A. ZEMAN
PRIMARY EXAMINER

January 31, 2008